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**Draft Pesticide Registration (PR) Notice 2016-X
For Public Comment – May 2016**

**NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS AND
REGISTRANTS OF PESTICIDE PRODUCTS**

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling

1. BRIEF OVERVIEW, PURPOSE AND APPLICABILITY

Pesticides can be used to control a variety of pests, such as insects, weeds, rodents, bacteria, fungi, etc. Over time many pesticides have gradually lost their effectiveness because pests have developed resistance – a significant decrease in sensitivity to a pesticide, which reduces the field performance of these pesticides. The Agency is concerned about resistance issues and believes that managing the development of pesticide-resistance, in conjunction with alternative pest-management strategies and Integrated Pest Management (IPM) programs, is an important part of sustainable pest management. To address the growing issue of resistance and preserve the useful life of pesticides, the Agency is beginning to embark on a more widespread effort and several activities are aimed at combating and slowing the development of pesticide resistance.

One of these activities is the concurrent but separate release of PR Notice 2016-XX, “Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship.” PR Notice 2016-XX, which only applies to herbicides, communicates the Agency’s current thinking and approach to address herbicide-resistant weeds by providing guidance on labeling, education, training, and stewardship for herbicides undergoing registration review or registration (i.e., new herbicide actives, new uses proposed for use on herbicide-resistant crops, or other case-specific registration actions). It is part of a holistic, proactive approach to slow the development and spread of herbicide-resistant weeds, and prolong the useful lifespan of herbicides and related

technology. The Agency is focusing on the more holistic guidance for herbicides first because they are the most widely used agricultural chemicals, no new herbicide mechanism of action has been developed in last 30 years, and herbicide-resistant weeds are rapidly increasing. In the future, the Agency plans to evaluate other types of pesticides (e.g. fungicides, bactericides, insecticides, and acaricides) to determine whether and what guidance may be appropriate for these types pesticides.

Another activity is the release of this PR Notice (2016-X). PR Notice 2016-X, which revises and updates PR Notice 2001-5, applies to all conventional, agricultural pesticides (*i.e.*, herbicides, fungicides, bactericides, insecticides and acaricides). Much of the content of this PRN is identical to the corresponding earlier guidance (PR Notice 2001-5). The updates in PR Notice 2016-X focus on pesticides labels and is aimed at improving information about how pesticide users can minimize and manage pest resistance. PR Notice 2016-X updates PRN 2001-5 with the following three categories of changes: (a) additional guidance to registrants, and a recommended format, for resistance management statements or information to place on labels; (b) references to external technical resources for guidance on resistance management; and (c) updates to the instructions on how to submit changes to existing labels in order to enhance resistance management language.

The Agency considers the development of pest resistance to be an adverse effect and believes that the kinds of statements articulated in this Notice can help crop producers minimize the likelihood of such resistance. Resistance management should maximize the tools available for growers to control problematic pests. It should also generally reduce pesticide loading in the environment and human exposure to pesticides, since growers facing widespread resistant pest populations may respond by increasing pesticide applications. In addition, for certain product reviews, EPA's risk-benefit determination and registration evaluation may be influenced by factors linked to pest resistance.

This PR Notice provides general guidance to EPA and to pesticide registrants and applicants, and the public. This guidance is not binding on either EPA or any outside parties, and the EPA may depart from the guidance when circumstances warrant and without prior notice. Registrants may propose alternative approaches to the recommendations in this PR Notice, and the Agency will assess them for appropriateness on a case-by-case basis.

2. EFFECTIVE DATE

Effective immediately once finalized.

3. SCOPE

This PR Notice addresses end-use herbicide, fungicide/bactericide, or insecticide/acaricide products that are intended for agricultural use. The recommendations regarding resistance-

management labeling herein are provided for both products that are being proposed for registration and currently registered products.

This guidance is not generally intended to apply to products labeled for the general consumer, such as residential or home-use pesticides.

This Notice also describes a recommended format for including useful resistance management information on pesticide labels.

4. BACKGROUND

Many pesticides registered in the U.S. already contain resistance management statements on their labeling. This underscores the value of this information to pesticide users and how it could contribute to delaying the development of pest resistance. Ideally, to address resistance effectively, registrants of all covered products would include such information on their products' labeling. As new developments unfold in the field of resistance management, there is a need to ensure that the warnings, restrictions, and recommended conditions of use stated on product labels continue to play a positive role in reducing the risk of resistance development.

Furthermore, in recent years, concerns for resistance developing in key pest areas have been intensifying. In addition, there has been a growing consensus within the stakeholder community that labeling-based means to help pesticide users manage resistance issues could be an important step in slowing resistance¹. The Agency is aware that not all pesticide labels provide the mode of action (MOA) of the pesticide active ingredient, and that some of those that do show this information do not describe the actions a pesticide user can take to avoid or delay the spread of resistance in pest populations. Going forward, the EPA wants to work toward having such resistance management information on all agricultural labels.

A. Science

What is “pest resistance”?

Pesticide resistance can be described as a heritable and significant decrease in the sensitivity of a pest population to a pesticide. Resistance reduces the field performance of pesticides. Pests include, among other things, insects, mites, weeds, fungi and bacteria. Managing the development of pesticide resistance is an important part of sustainable pest management, and this, in conjunction with alternative pest-management strategies and IPM programs, assists crop producers to manage pests in a sustainable manner. In support of this goal, the purpose of this Notice is to provide registrants with updated guidance on resistance-management labeling, and its implementation on existing labels.

¹ See, for example, Norsworthy, J.K., *et al.* (2012). Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations. Weed Science Special Issue: 31–62.

What causes pest resistance; how does it happen?

In general, pesticide resistance occurs when genetic or behavioral changes enable pest individuals to tolerate or survive what would otherwise be lethal doses of a pesticide and then spread those changes through the larger pest population. These changes are usually biochemical in nature (e.g., genes allowing metabolic detoxification of a pesticide occur as a result of random mutation, and these in turn allow pest individuals to survive repeated and/or lower dose applications of a given pesticide). If a pesticide is not rotated with other chemicals with different modes of action over several applications, and/or if that pesticide is not used at a dose lethal enough to kill almost all of the pest population, then the genes responsible for the resistant trait can spread quickly through the population (*i.e.*, pesticide susceptible individuals are killed off, but resistant ones that are not challenged by pesticides with different modes of action can then mate with one another and make the resistance trait more common over time).

Generally, how common / widespread is pest resistance?

Resistance appears to be generally increasing in the United States and worldwide. For example, globally the number of unique herbicide-resistant weed species has risen from one in 1957 to over 440 in 2014 (www.weedscience.org). Between 1908 and 2012, the number of insecticide-resistant arthropod species has risen from one to 574 (www.pesticideresistance.org). A major factor that fosters resistance development is a lack of understanding of resistance-management options available to crop producers who use pesticides routinely².

What are the concepts that guide resistance-management strategies?

EPA supports broader efforts at developing comprehensive resistance-management strategic plans that may take into account local conditions, soil management, crop rotation, cultural approaches and other factors. Resistance-management labeling will provide pesticide users with easy access to important information regarding target-site resistance, the cornerstone of most resistance-management programs.

Development of pest resistance is influenced by a number of factors. One important factor is the repeated use of pesticides with the same mode of action on the same pest population. Thus, an important proactive pesticide resistance-management strategy is to rotate pesticides with different modes of action to control target pests in any given location. This approach may delay the development of one important type of resistance, target-site resistance, without resorting to increased rates and frequency of application, and may prolong the useful life of pesticides.

² See, for example, Prince, J.M. *et al.* (2012). A 2010 Survey to Assess Grower Awareness of and Attitudes toward Glyphosate resistance. *Weed Technology* 26: 531-535.

If pesticides are used in a manner that facilitates the development and/or spread of resistance in target pest populations, pesticide users are likely to increase their use of multiple pesticides in attempts to manage pests. This in turn would increase loading of pesticides in the environment, with the potential for unintended consequences such as increased impacts on non-target wildlife and increased exposure to humans. Without appropriate actions to manage resistance, target pests would eventually show widespread resistance that no management tactic could adequately address, thus leading to potentially significant crop losses. Pesticide users look to product labeling as a primary source for their use instructions, and resistance-management guidance on labels could significantly and immediately assist users to avoid or delay the spread of resistance in pests. The Agency has found pesticide resistance to be an adverse effect, and the lack of appropriate resistance-management guidance on labels may become a factor that could strongly influence EPA's regulatory conclusions on the risks and benefits of a pesticide.

5. GUIDANCE: MODE OF ACTION GROUPING AND IDENTIFICATION SYMBOLS

To ensure consistency in pesticide grouping and labeling, and to contribute to the management of pesticide resistance, the following guidelines have been developed for agricultural uses of herbicides, fungicides/bactericides, and insecticides/acaricides. The classification schemes shown in this section are based on the mode of action. Herbicides, fungicides/bactericides, and insecticides/acaricides are separately grouped according to their primary modes of action by various Resistance Action Committees (RACs). Typically, these committees consist of representatives of the pesticide industry, researchers, extension specialists and regulatory officials. The pesticide groupings are provided by the Weed Science Society of America (WSSA; <http://www.wssa.net/>), the Herbicide Resistance Action Committee (HRAC; <http://www.hracglobal.com/>), the Fungicide Resistance Action Committee (FRAC; <http://www.frac.info/>) and the Insecticide Resistance Action Committee (IRAC; <http://www.irac-online.org/>). The mode of action groups plus the identifier numbers and/or letters (i.e., symbols or codes) for herbicides, fungicides/bactericides and insecticides/acaricides may be accessed through the websites of the different Resistance Action Committees (listed in the following paragraphs).

WSSA uses numbers 1 through 30 to identify the MOA groups for herbicides. The number 26 is used for compounds with a non-classified MOA. For herbicides, EPA recommends that the WSSA MOA identifier codes be used to ensure consistency with existing herbicide labels that follow this scheme. HRAC uses alphabetical letters instead of numbers for the MOA groups for herbicides. The HRAC website contains a cross reference between the HRAC and the WSSA MOA identifier codes; the WSSA MOA codes can be found at the following HRAC website:

<http://www.hracglobal.com/pages/classificationofherbicidesiteofaction.aspx>.

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For fungicides, FRAC uses different letters (A to I, with added numbers) to distinguish fungicide groups according to their biochemical MOA in the biosynthetic pathways of plant pathogens. EPA recommends that the FRAC MOA identifier codes be used for designating fungicide mode of action grouping information on labels for pesticides containing fungicides. The FRAC code list can be found at: <http://www.frac.info>, where the reader is advised to use the search term “code list” in the site’s search function to locate the most current groupings.

For insecticides, IRAC uses a combination of numbers and letters to identify various MOA groups. EPA recommends that the IRAC MOA identifier codes be used for designating insecticide mode of action grouping information on labels for pesticide containing insecticides. The IRAC MOA list and identifier codes can be found at: <http://www.irac-online.org/modes-of-action/>.

EPA recommends that the mode of action identification symbol be shown on the end-use product label in a mode of action information box following the standard format outlined below. A standard format across pesticide labels should help the end-user to more quickly locate and utilize the technical information being conveyed.

Location: Upper right corner of front panel of label

Content:

- Include the name of the **ACTIVE INGREDIENT** in the first column
- Include the word “**GROUP**” in the second column
- Include the **MODE OF ACTION CODE** in the third column
- Include the type of pesticide (i.e., **HERBICIDE** or **FUNGICIDE** or **INSECTICIDE**) in the fourth column;

Appearance: All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.

Figure 1 below illustrates the format of the mode of action information box that the Agency suggests for agricultural pesticide labels. Figure 2 below shows an example of the mode of action information box appropriate for an aldicarb product.

Figure 1. Recommended pesticide mode of action information box format.

NAME of ACTIVE INGREDIENT	GROUP	MODE OF ACTION CODE as Designated by WSSA, FRAC, or IRAC	Type of Pesticide, <i>e.g.</i> “ HERBICIDE ”, “ INSECTICIDE ”, “ FUNGICIDE ”, etc
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Figure 2. Example of pesticide mode of action information box for a pesticide containing aldicarb.

ALDICARB	GROUP	1A	INSECTICIDE
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EPA is also revising Chapter 11.VI.G of the Office of Pesticide Programs' Label Review Manual (LRM) to include additional examples or information that addresses other considerations, such as:

- Products containing a single active ingredient that has multiple modes of action group codes across different pesticide types.
- Products containing multiple active ingredients.
- Products containing mixtures of different pesticide types (e.g., a fungicide mixed with an insecticide).
- Pesticide products packaged in separate containers but sold together as a single unit (i.e., co-packs).

The suggested revisions to Chapter 11.VI.G of the LRM are shown in USEPA, 2016 (see reference list).

6. GUIDANCE: GENERAL RESISTANCE-MANAGEMENT STATEMENTS

Resistance-management statements are recommended to be included within the Directions for Use section of the label under the heading **Resistance-Management Recommendations**. The recommended standard resistance-management labeling statements listed below focus on the mitigation of pest resistance and should be used where applicable based on the availability of other pesticides and production practices specific to that crop. These recommendations should also be included in any product-specific literature.

A. Herbicides

1. The following general resistance management labeling statements are recommended for herbicide products containing only a single active ingredient or multiple active ingredients that are from the same mode of action group:

“For resistance management, (name of product) is a Group (mode of action

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group number) herbicide. Any weed population may contain or develop plants naturally resistant to (name of product) and other Group (mode of action group number) herbicides. The resistant biotypes may dominate the weed population if these herbicides are used repeatedly in the same field. Appropriate resistance-management strategies should be followed.”

For products containing active ingredients from different groups, the statement should be modified to reflect the situation. For example:

“For resistance management, please note that (name of product) contains both a Group (mode of action group number)/[common name] and a Group (mode of action group number)/[common name] herbicide. Any weed population may contain plants naturally resistant to Group (mode of action group number) and/or Group (mode of action group number) herbicides. The resistant individuals may dominate the weed population if these herbicides are used repeatedly in the same fields.” Appropriate resistance-management strategies should be followed.”

2. The following additional resistance management labeling statements are recommended for herbicides, although each bulleted statement may not be appropriate or pertinent for every product label:

“To delay herbicide resistance take one or more of the following steps:

- Rotate the use of (name of product) or other Group (mode of action group number) herbicides within a growing season sequence or among growing seasons with different herbicide groups that control the same weeds in a field.
- Use tank mixtures with herbicides from a different group if such use is permitted; where information on resistance in target weed species is available, use the less resistance-prone partner at a rate that will control the target weed(s) equally as well as the more resistance-prone partner. Consult your local extension service or certified crop advisor if you are unsure as to which active ingredient is currently less prone to resistance.
- Adopt an integrated weed management program for herbicide use that includes scouting and uses historical information related to herbicide use and crop rotation, and that considers tillage (or other mechanical control methods), cultural (e.g., higher crop seeding rates; precision fertilizer application method and timing to favor the crop and not the weeds), biological (weed-competitive crops or varieties) and other management practices.

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- Scout after herbicide application to monitor weed populations for early signs of resistance development. Indicators of possible herbicide resistance include: (1) failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds; (2) a spreading patch of non-controlled plants of a particular weed species; (3) surviving plants mixed with controlled individuals of the same species. If resistance is suspected, prevent weed seed production in the affected area by an alternative herbicide from a different group or by a mechanical method such as hoeing or tillage. Prevent movement of resistant weed seeds to other fields by cleaning harvesting and tillage equipment when moving between fields, and planting clean seed.
- If a weed pest population continues to progress after treatment with this product, discontinue use of this product, and switch to another management strategy or herbicide with a different mode of action, if available.
- Contact your local extension specialist or certified crop advisors for additional pesticide resistance-management and/or integrated weed-management recommendations for specific crops and weed biotypes.
- For further information or to report suspected resistance, contact (company representatives) at (toll-free number) or at (Internet site).”

In addition to the guidance above, registrants are encouraged to incorporate the appropriate elements of Best Management Practices from HRAC and WSSA on the label.

B. Fungicides and Bactericides

1. The following general resistance management labeling statements are recommended for fungicide/bactericide products containing only a single active ingredient or multiple active ingredients that are from the same mode of action group:

“For resistance management, (name of product) contains a Group (mode of action group number) fungicide/bactericide. Any fungal/bacterial population may contain individuals naturally resistant to (name of product) and other Group (mode of action group number) fungicides/bactericides. A gradual or total loss of pest control may occur over time if these fungicides/bactericides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.”

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For products containing two or more active ingredients from different groups, the statement should be modified to reflect the situation. For example:

“For resistance management, please note that (name of product) contains both a Group (mode of action group number)/ [common name] and Group (mode of action group number)/ [common name] fungicide/bactericide. Any fungal/bacterial population may contain individuals naturally resistant to (name of product) and other Group (mode of action group number) or Group (mode of action group number) fungicides/bactericides. A gradual or total loss of pest control may occur over time if these (fungicides/bactericides) are used repeatedly in the same fields.” Appropriate resistance-management strategies should be followed.”

2. The following additional resistance management labeling statements are recommended for fungicides/bactericides, although each bulleted statement may not be appropriate or pertinent for every product label:

“To delay fungicide/bactericide resistance, take one or more of the following steps:

- Rotate the use of (name of product) or other Group (mode of action group number) fungicides/bactericides within a growing season sequence, or among growing seasons, with different groups that control the same pathogens.³
- Use tank mixtures with fungicide/bactericides from a different group that are equally effective on the target pest when such use is permitted.
- Adopt an integrated disease management program for fungicide/bactericide use that includes scouting, uses historical information related to pesticide use, and crop rotation, and which considers host plant resistance, impact of environmental conditions on disease development, disease thresholds, as well as cultural, biological and other chemical control practices.
- Where possible, make use of predictive disease models to effectively time fungicide/bactericide applications.
- Monitor treated fungal/bacterial populations for resistance development.

³ If repeated application is necessary, this statement may be modified as follows: “Avoid application of more than (maximum number of applications) and consecutive sprays of (name of product) or other (fungicides/bactericides) in the same group in a season.”

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- If disease continues to progress after treatment with this product, discontinue use of this product, and switch to another management strategy or fungicide/bactericide with a different mode of action, if available.
- Contact your local extension specialist or certified crop advisor for any additional pesticide resistance-management and/or IPM recommendations for specific crops and pathogens.
- For further information or to report suspected resistance contact (company representatives) at (toll-free number) or at (Internet site).”

C. Insecticides and Acaricides

1. The following general resistance management labeling statements are recommended for insecticide/acaricide products containing only a single active ingredient or multiple active ingredients that are from the same mode of action group:

“For resistance management, (name of product) contains a Group (mode of action group number) insecticide (or acaricide). Any (insect/mite) population may contain individuals naturally resistant to (name of product) and other Group (mode of action group number) insecticides/acaricides. The resistant individuals may dominate the insect/mite population if this group of insecticides/acaricides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.”

For products containing two or more active ingredients from different groups, the statement should be modified to reflect the situation. For example:

“For resistance management, please note that (name of product) contains both a Group (mode of action group number)/ [common name] and Group (mode of action group number)/ [common name] insecticides/acaricides. Any insect/mite population may contain individuals naturally resistant to (name of product) and other Group (mode of action group number) or Group (mode of action group number) insecticides/ acaricides. The resistant individuals may dominate the insect/mite population if these insecticides/acaricides are used repeatedly in the same fields.” Appropriate resistance-management strategies should be followed.”

2. The following additional resistance management labeling statements are recommended for insecticides/acaricides, although each bulleted statement may not be appropriate or pertinent for every product label:

“To delay insecticide/acaricide resistance, take the following steps:

- Rotate the use of (name of product) or other Group (mode of action group number) insecticides/acaricides within a growing season, or among growing seasons, with different groups that control the same pests.⁴
- Use tank mixtures with insecticides/acaricides from a different group that are equally effective on the target pest when such use is permitted.
- Adopt an integrated pest management program for insecticide/acaricides use that includes scouting, uses historical information related to pesticide use, crop rotation, record keeping, and which considers cultural, biological and other chemical control practices.
- Monitor treated pest populations for resistance development.
- If an insect pest population continues to progress after treatment with this product, discontinue use of this product, and switch to another management strategy or insecticide with a different mode of action, if available.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific site and pest problems in your area.
- For further information or to report suspected resistance contact (company representatives) at (toll free number) or at (Internet site).”

Registrants of products with known resistance issues should also consider including product-specific use directions, in addition to the recommendations described in Sections 5 and in this section. While general information such as the mode of action symbol or number and resistance management statements give guidance to users on how to maintain long-term pesticide performance, product-specific use directions can tell users exactly how they must apply a particular pesticide product. Product-specific use directions might include, for example, instructions to tank mix a pesticide with a pesticide from a different mode of action group, or advising that no more than two sequential applications may be made before switching to a pesticide with a different mode of action.

Similarly, registrants of active ingredients that already have widespread resistance concerns are strongly encouraged to include both general and product-specific use directions on their

⁴ If a number of applications are necessary each year on a pest-by pest basis, this statement may be modified as follows: “Avoid application of more than (maximum number) and consecutive sprays of (name of product) or other insecticides in the same group in a season.”

labels. The Agency believes that including additional, product-specific use directions will provide the best possible guidance to users of pesticides and will reduce the likelihood of resistance developing in target pest populations in their localities.

7. PESTICIDES OF UNSPECIFIED GROUPS

EPA believes that all agricultural products should have the appropriate resistance-management information (based on the availability of other pesticides and the production practices specific to that crop) articulated by this Notice, including those that have an unknown mechanism of action or are operative with multi-site activity. In this way, the concepts of season-long rotation among different MOA categories can be more fully and appropriately addressed by pesticide end users.

Some herbicides, fungicides, bactericides, insecticides and acaricides have not been assigned to any particular mode of action group because of the lack of clear understanding of their mode of action or the absence of a history of resistance development for the product. Nonetheless, EPA strongly encourages registrants to establish the appropriate group identifications for their products, in consultation with representatives of the pesticide industry, technical working groups such as IRAC, HRAC, and FRAC, researchers, extension specialists and regulatory officials, if appropriate. Even if a MOA group identification is not yet available, the use directions should include other appropriate resistance-management statements for the product, *i.e.*, herbicides, fungicides/ bactericides and insecticides/acaricides, as suggested in the sections above.

The pesticide classification schemes are updated from time to time to include product names and/or new/revised site/mode of action classification. Information regarding new or revised mode of action classification may be obtained from the websites of the appropriate resistance action committees.

8. PAPERWORK REDUCTION ACT (PRA) NOTICE

Under the PRA, “burden” means the total time, effort or financial resources expended by persons to generate, maintain, retain or disclose or provide information to or for a Federal agency. The registrant/applicant may incur a burden from the following activities associated with this PR Notice:

- 1) Reading and understanding this PR Notice,
- 2) Incorporating information into labels or making revisions to pesticide product labels consistent with a pesticide’s pest resistance concern category and associated recommended resistance management elements,

The information-collection activities associated with the activities described in this PR Notice are already approved by the Office of Management and Budget (OMB) under the

Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., under several Information Collection Request (ICR) documents.

Reading and understanding this PR Notice is not expected to be a recurring burden for applicants. Similarly, revising product labels with resistance management label language are largely one-time activities for each herbicide. These activities are expected to occur as part of the standard registration and reevaluation processes.

The ICR document for the Pesticide Data Call-In Program has been assigned EPA ICR Number 2288.02 and is approved under OMB control number 2070-0174. This ICR captures the burden of activities 1, and 2 above for registrants implementing pesticide resistance label language for registered herbicides at the time the chemical undergoes registration review. Typical activities include reading and understanding relevant PR Notices and submitting appropriate paperwork, including any label changes.

The ICR document for the Application for New and Amended Pesticide Registration has been assigned EPA ICR Number 0277.16 and is approved under OMB control number 2070-0060. This ICR captures the burden of activities 1, and 2 above for registrants implementing pesticide resistance measures for new chemicals and uses at the time of registration. The annual average burden for the application process is estimated to be 14 hours for a conventional pesticide registration (see Type A action) to 646 hours for a conventional pesticide documenting reduced risk in comparison to existing alternatives (see Type C action)⁵. These actions also include over 45,000 hours associated with generating data to support the registrations. The burden associated with the application process includes reading and understanding germane PR Notices and gathering and creating information needed to support a registration, including the label and other labeling and supporting documents. Of these hours, the estimated annual applicant burden to follow the guidance suggested in this PR Notice is approximately 1 hour. This burden is expected to be the same regardless of which “Type” of applicant activity is considered, because in all cases registrants should be able to quickly gather the requested label information from the PRN itself or (for mode of action groupings) the industry’s own RACs which are described in the Notice. Based on past applications, EPA estimates there are 205 new active ingredient and new-use applications, of which 167 are for conventional pesticides; the remaining are for antimicrobial pesticides and biopesticides.

9. WHAT APPLICANTS AND REGISTRANTS SHOULD DO

In order to support the policy goals of this Notice, EPA encourages registrants to add the appropriate resistance-management statements through any of the Agency’s regulatory mechanisms. In particular, the addition of these proposed statements will be permitted by (1)

⁵ Type B actions are new products or label amendments, which would not necessitate implementing herbicide resistance management measures.

notification, (2) amendment or (3) as part of an application for a new product. The addition of the statements identified in this Notice, without other changes, will not result in the imposition of fees in association with the Pesticide Registration Improvements Act (PRIA) because Agency-initiated label amendments are not subject to PRIA.

A. New Product Submissions

Registrants are strongly encouraged to include the resistance management labeling described in this Notice, as appropriate, as part of new product submissions. EPA intends to consult this guidance when reviewing the resistance-management labeling sections for pending applications for registration of a new pesticide product before making a determination on registration.

B. How to Revise Labeling for Existing Products

1. Notification

Registrants who adopt the exact wording set forth in this Notice, as appropriate to their particular product, and who make no other labeling changes may submit a revised label via notification.

The registrant should submit one copy of the label (with changes clearly marked in a way that can be photocopied) along with a completed Application for Registration (EPA Form 8570-1). Registrants can utilize the Web-based Pesticide Submission Portal (PSP) described in the section immediately following below. Unless the registrant specifies that it has made any other changes to the labeling, the Agency will assume the ONLY labeling changes made are to incorporate the resistance management language, or, in addition, other labeling changes permitted via notification. If other changes have been made to the labeling without written notice, EPA will consider referring such submission to the proper authorities under 18 USC 1001. Under 18 USC 1001, it is unlawful to knowingly and willfully make false statements to the government. Lastly, if labeling changes through notification under this PR Notice are not consistent with the procedures established in this PR Notice and the requirements of 40 CFR Part 156, the product may be in violation of FIFRA and may be subject to enforcement action and penalties. The application form should bear the following statement:

"Notification of label change per PR Notice 2016-X. This notification is consistent with the guidance in PR Notice 2016-X regarding resistance management and the requirements of EPA's regulations at 40 CFR Part 156. Only changes that are permitted via notification are made on the submitted label. I understand that it is a violation of 18 U.S.C. Sec. 1001 to knowingly and willfully make any false statement to EPA. I further understand that if this notification is not consistent with the guidance of PR Notice 2016-X and the requirements of

40 CFR Part 156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

EPA will review the Notification and determine whether the proposed changes fall within the scope of PR Notice 2016-X. Registrants will be notified in writing of the Agency's decision.

2. Amendment

An amendment is appropriate for labeling changes that cannot be implemented via notification. If the registrant wishes to propose alternative wording from that set forth in this Notice or if the registrant wishes to use the wording in this Notice but also make other label changes, then the revised label must be submitted as an Amendment.

The registrant should submit a completed Application for Registration (EPA Form 8570-1), as provided in 40 CFR §152.50, along with proposed labeling. The application should include an explanation as to why alternate language is appropriate. If the only label change proposed is adding or revising resistance management language, the amendment would be a fast-track amendment that does not require the submission of registration service fees under the Pesticide Registration Improvement Act (PRIA). PRIA fees may apply if other labeling changes are proposed (for example, if such a change required a data review). EPA will review the amendment application and determine whether the proposed changes are acceptable. Registrants will be notified in writing of the Agency's decision.

For amendments containing only changes in resistance management labeling but which involve the registrant's own unique text, the application form should bear the following statement:

"I certify that the revised labeling is being submitted consistent with the guidance contained in PR Notice 2016-X. This amendment pertains to the guidance in PR Notice 2015-X regarding resistance management and the requirements of EPA's regulations at 40 CFR Part 156. Unique resistance management text is being proposed. However, no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to knowingly and willfully make any false statement to EPA."

With this certification, the Agency will assume the ONLY label changes made are to incorporate the resistance management language. If other changes have been made to the labeling without written notice, EPA will consider referring such submission to the proper authorities under 18 USC 1001. Under 18 USC 1001, it is unlawful to knowingly and willfully make false statements to the government.

10. HOW TO SUBMIT AN APPLICATION

With the availability of the Web-based Pesticide Submission Portal (PSP) within EPA's Central Data Exchange (CDX) Network, registrants have the ability to submit new product submissions, notifications, and amendments electronically either via a secure webpage or by CD/DVD. Further guidance on how to submit applications electronically to OPP is available at <http://www.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>. While electronic submission is not mandatory, it will greatly facilitate EPA's review process, as well as eliminate the need for submission of multiple copies of the proposed label.

A. Fully Electronic Application

Fully electronic applications may be submitted either via the PSP website or on a CD/DVD mailed to EPA's Document Processing Desk. Applicants should submit electronically an Application for Registration/Amendment (EPA Form 8570-1) and an electronic copy of the proposed label in PDF format. The EPA has established a website to help pesticide registrants to format and submit their electronic submissions properly. For more information, visit <http://www.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>. For additional assistance, registrants can email the E-submission Help Desk at OPPeSubmissionHelpdesk@epa.gov or call toll-free 1-866-612-8664. The appropriate submission code (REGFEE or AMEND-RESISTANCE MANAGEMENT or NOTIF-RESISTANCE MANAGEMENT) should appear on the first page of the transmitting cover letter.

B. Partial Electronic Application (Paper Forms with Electronic Label on CD/DVD)

Applicants should submit a paper Application for Registration/Amendment (EPA Form 8570-1), one paper copy of the proposed label, and an electronic copy of the proposed label in PDF format on a CD-ROM or DVD. Guidance for creating an electronic label can be found at <http://www.epa.gov/pesticide-registration/electronic-submission-labels>. The appropriate submission code (REGFEE or AMEND-RESISTANCE MANAGEMENT or NOTIF-RESISTANCE MANAGEMENT) should appear on the first page of the transmitting cover letter.

C. Paper Application

Applicants should submit a paper Application for Registration/Amendment (EPA Form 8570-1), and four (4) copies of revised labeling. Label changes on Notifications should be clearly marked in a way that can be photocopied while label changes on Amendments should not be marked. The appropriate submission code (REGFEE or AMEND-RESISTANCE MANAGEMENT or NOTIF RESISTANCE MANAGEMENT) should appear on the first page of the transmitting cover letter.

11. Timeline for Implementation

The Agency expects registrants of products covered by this Notice to follow the procedures explained in Section 9 of this Notice and then, within two years after publication of a final Notice, to add language addressing resistance management to the labels of their pesticide products as appropriate.

12. Addresses

Registrants should send paper submissions to one of the following addresses:

U.S. Postal Service Deliveries

Document Processing Desk (NOTIF-RESISTANCE MANAGEMENT or AMEND-RESISTANCE MANAGEMENT)

Product Manager Name (RD/BPPD/AD)

Office of Pesticide Programs (7504P)

U. S. Environmental Protection Agency

1200 Pennsylvania Ave., NW

Washington, DC 20460-0001

Personal/Courier Service Deliveries (e.g., FedEx)

For submissions that are hand-carried or sent by courier service (send only Monday through Friday, from 8:00 am to 4:30 pm, excluding Federal holidays):

Document Processing Desk (NOTIF-RESISTANCE MANAGEMENT or AMEND-RESISTANCE MANAGEMENT)

Product Manager Name (RD/BPPD/AD)

Office of Pesticide Programs (7504P)

U. S. Environmental Protection Agency

Room S-4900, One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202-4501

13. Further Information

The Office of Pesticide Programs is developing a webpage to provide information and updates on resistance management within the program.

If you have general questions about this PR Notice or about resistance management labeling, please contact the pesticide Product Manager or:

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Office of Pesticide Programs
U.S. Environmental Protection Agency
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1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001
Telephone: 703-308-1924
E-mail: Mallampalli.Nikhil@epa.gov

14. References

USEPA. 2016. Draft - Recommended Revisions to Chapter 11.VI.G of EPA's Office of Pesticide Programs' Label Review Manual.